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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,570

09/15/2003

Luc R. Mongcon

1023-203US01

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.		Applicant(s)	
	10/663,570		MONGEON ET AL.	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-45 is/are pending in the application.
- 4a) Of the above claim(s) 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-4 and 9-34 in the reply filed on 11/22/2006 is acknowledged. The traversal is on the ground(s) that the method of manufacturing claims (35-42) do not require that the genetic material be introduced into the matrix before insertion into the chamber body. This admission is found persuasive, thus the restriction requirement between claims [1-4 and 9-34] and 35-42 is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4 and 10-42 rejected under 35 U.S.C. 102(b) as anticipated by Soykan et al. (US 6,151,525, hereinafter "Soykan") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Soykan in view of Heil, Jr. et al. (US 4,819,662, hereinafter "Heil").

6. In regards to claims 1, 21, and 35, Soykan discloses a method/system comprising a lead for delivering electrical stimulation to tissue (col. 13, line 38) and eluting genetic material from a polymeric matrix (col. 11, line 1) to cause transgenic expression. Further, because the matrix is "incorporated in" the carrier, the matrix is inherently in a chamber body. Alternatively, Heil teaches of providing a lead with a chamber for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's invention by providing a lead with a chamber for the purpose of providing controlled release of agents at the site of electrical therapy.

7. In regards to claims 2 and 22, Soykan discloses that the matrix is extracellular collagen (col. 11, line 47).

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8. In regards to claims 4, 23 and 37, the matrix is cross-linked (col. 11, line 55).

The level of cross-linking is inherently proportional to the release rate.

9. In regards to claims 10 and 26, the delivery vector is a liposome (claim 7).

10. In regards to claims 11 and 27, the genetic material causes expression of contractile cells (abstract), which increases the conductivity of the cells.

11. In regards to claims 14 and 30, the genetic material causes expression of an immunosuppressant agent (col. 6, line 1).

12. In regards to claims 16 and 17, a genetic material and dexamethasone are delivered (col. 11, line 35).

13. In regards to claims 18 and 32, the electrode is implantable (col. 13, line 49).

14. In regards to claims 19 and 33, the tissue is cardiac tissue (abstract).

15. In regards to claims 20 and 34, because the method is providing contractile tissue between the stimulator and healthy tissue, the method creates a preferential conduction pathway between the stimulation site and intrinsic conduction system.

16. Claims 3, 12, 13, 15, 28, 29, 31, 36, and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan (or Soykan in view of Heil). Soykan (or Soykan in view of Heil) discloses the essential features of the claimed invention, including using autologous biological material (col. 5, line 67) that is incorporated just prior to delivery by swelling the hydrogel (col. 11, line 59), but does not disclose a freeze-dried (lyophilized) or frozen matrix, a genetic material causing expression of connexin or I κ B, placing the matrix in the lead just before implantation, or soaking of the

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distal end of the lead in the genetic material. It is well known in the art to freeze-dry or freeze matrix to increase the shelf-life of the biologically active substance, to provide a genetic material causing expression of connexin or I κ B to improve the conductive quality of cardiac tissue, and to soak (or swell) matrix in genetic material before placement into the body (either before delivery, or right at delivery) to allow autologous biological substances to be implanted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's (or Soykan in view of Heil's) invention by freeze-drying or freezing matrix to increase the shelf-life of the biologically active substance, providing a genetic material causing expression of connexin or I κ B to improve the conductive quality of cardiac tissue, and soaking matrix in genetic material before placement into the body to allow autologous biological substances to be implanted.

17. Claims 9, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Heil. Soykan discloses the essential features of the claimed invention except for eluting the material via a porous electrode, or a chamber body that is separable from the lead body. Heil teaches of providing an implantable lead with a porous electrode (32) to provide controlled elution of an agent placed in a chamber within the lead, and a chamber body that is separable from the lead body (Fig. 7) to allow loading of the agent at the time of implantation (col. 6, line 60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Soykan's invention with a porous electrode to provide controlled

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elution of an agent placed in a chamber within the lead, and a chamber body that is separable from the lead body to allow loading of the agent at the time of implantation.

Response to Arguments

18. Applicant's arguments, see "Remarks", filed 8/4/2006, with respect to the rejection(s) of claim(s) 1-35 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new art.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nabel et al. (US 5,328,470) is one of many teachings of assembling a biological material administration kit just before delivery and freeze-drying matrix; Girouard et al. (US 2004/0158289) is one of many teachings of administering connexin-43; and Palasis et al. (US 6,749,617) is one of many teachings of providing IkB to cardiac tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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3/26/07

GE
GEORGE R. EVANISKO
PRIMARY EXAMINER

3/26/7